

Appln No.: 08/935,717
Amendment Dated: June 25, 2004
Reply to Office Action of March 25, 2004

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-10. (canceled)

11. (currently amended) A test kit for determining qualitatively or quantitatively the presence of an analyte in a fluid sample, said test kit comprising:

- (a) an assay device, said assay device having a detection zone, wherein the presence of the analyte in the fluid sample is indicated by accumulation of a labeled reagent within the detection zone; and
- (b) a reading device effective to detect labeled reagent, said reading device comprising means for initiation of the reading device to detect labeled reagent in the detection zone,

wherein said means for initiation of the reading device engages the assay device in a lock-and-key interaction, thereby forming a lock-and-key interaction between the reading device and the assay device whereby the reading device is initiated in response to and only when said assay device is properly positioned in lock-and-key engagement within said reading device and the lock-and-key interaction is formed.

12. (previously presented) The test kit of claim 11, wherein said assay device comprises a porous carrier strip disposed within a hollow casing, said porous carrier strip having the detection zone, and wherein an assay result is revealed by specific binding of the labeled reagent within the detection zone.

13. (previously presented) The test kit of claim 12, wherein the means for initiation of said reading device comprises a switch actuator, and wherein said assay device comprises a contact portion, said contact portion and said switch actuator engaging in a lock-and-key engagement.

14. (previously presented) The test kit of claim 13, wherein the switch actuator comprises a fixed projecting portion and a displaceable projecting portion, and wherein the contact portion has

a recess for receiving the fixed projecting portion, but not the displaceable projecting portion, when the assay device is correctly positioned in the reading device; and
an interface portion that contacts and displaces the displaceable projecting portion when the assay device is correctly positioned in the reading device.

Appln No.: 08/935,717
Amendment Dated: June 25, 2004
Reply to Office Action of March 25, 2004

15. (previously presented) The test kit of claim 13, wherein the reading device further comprises means for pressing an assay device inserted into the reading device against the switch actuator.

16. (previously presented) The test kit of claim 15, wherein the reading device further comprises a cam that deflects the assay device away from the switch actuator unless the assay device is correctly positioned within the reading device.

17. (currently amended) The test device kit of claim 16, wherein the assay device is elongate, and wherein the reading device has a slot into which the assay device is at least partially inserted through a mouth for reading of the assay device, and wherein the slot has at least one projecting lip portion extending over the mouth of the slot, said lip portion acting to retain the assay device within the slot when correctly positioned therein.

18. (previously presented) The test kit of claim 17, wherein the projecting lip portion is disposed at an end of the slot, and engages an end of the elongate assay device during insertion of the assay device into the slot.

19. (previously presented) The test kit of claim 11, wherein the means for initiation of said reading device comprises a switch actuator, and wherein said assay device comprises a contact portion, said contact portion and said switch actuator engaging in a lock-and-key engagement.

20. (previously presented) The test kit of claim 19, wherein the switch actuator comprises a fixed projecting portion and a displaceable projecting portion, and wherein the contact portion has
a recess for receiving the fixed projecting portion, but not the displaceable projecting portion, when the assay device is correctly positioned in the reading device; and
an interface portion that contacts and displaces the displaceable projecting portion when the assay device is correctly positioned in the reading device.

21. (previously presented) The test kit of claim 19, wherein the reading device further comprises means for pressing an assay device inserted into the reading device against the switch actuator.

22. (previously presented) The test kit of claim 21, wherein the reading device further comprises a cam that deflects the assay device away from the switch actuator unless the assay device is correctly positioned within the reading device.

Appln No.: 08/935,717

Amendment Dated: June 25, 2004

Reply to Office Action of March 25, 2004

23. (currently amended) The test device kit of claim 22, wherein the assay device is elongate, and wherein the reading device has a slot into which the assay device is at least partially inserted through a mouth for reading of the assay device, and wherein the slot has at least one projecting lip portion extending over the mouth of the slot, said lip portion acting to retain the assay device within the slot when correctly positioned therein.

24. (previously presented) The test kit of claim 23, wherein the projecting lip portion is disposed at an end of the slot, and engages an end of the elongate assay device during insertion of the assay device into the slot.

25. (previously presented) The test kit of claim 11, wherein the switch actuator comprises a fixed projecting portion and a displaceable projecting portion, and wherein the contact portion has
a recess for receiving the fixed projecting portion, but not the displaceable projecting portion, when the assay device is correctly positioned in the reading device; and
an interface portion that contacts and displaces the displaceable projecting portion when the assay device is correctly positioned in the reading device.

26. (previously presented) The test kit of claim 25, wherein the reading device further comprises means for pressing an assay device inserted into the reading device against the switch actuator.

27. (previously presented) The test kit of claim 26, wherein the reading device further comprises a cam that deflects the assay device away from the switch actuator unless the assay device is correctly positioned within the reading device.

28. (currently amended) The test device kit of claim 27, wherein the assay device is elongate, and wherein the reading device has a slot into which the assay device is at least partially inserted through a mouth for reading of the assay device, and wherein the slot has at least one projecting lip portion extending over the mouth of the slot, said lip portion acting to retain the assay device within the slot when correctly positioned therein.

29. (previously presented) The test kit of claim 28, wherein the projecting lip portion is disposed at an end of the slot, and engages an end of the elongate assay device during insertion of the assay device into the slot.

30. (currently amended) A test kit for determining qualitatively or quantitatively the presence of an analyte in a fluid sample, said test kit comprising:

Appln No.: 08/935,717
Amendment Dated: June 25, 2004
Reply to Office Action of March 25, 2004

- (a) an assay device, said assay device having a detection zone, wherein the presence of the analyte in the fluid sample is indicated by accumulation of a labeled reagent within the detection zone; and
- (b) a reading device effective to detect labeled reagent, said reading device comprising means for initiation of the reading device to detect labeled reagent in the detection zone,
wherein said means for initiation of the reading device engages the assay device in a lock-and-key interaction, whereby the reading device is initiated in response to and only when said assay device is properly positioned in lock-and-key engagement within said reading device. The test device of claim 11; wherein the assay device is elongate, and wherein the reading device has a slot into which the assay device is at least partially inserted through a mouth for reading of the assay device, and wherein the slot has at least one projecting lip portion extending over the mouth of the slot, said lip portion acting to retain the assay device within the slot when correctly positioned therein.

31. (canceled)

32. (currently amended) The test kit of claim 11, wherein the means for initiation of said reading device comprises a switch actuator, and wherein said assay device comprises a contact portion, said contact portion and said switch actuator engaging in a lock-and-key engagement.

33. (previously presented) The test kit of claim 32, wherein the switch actuator comprises a fixed projecting portion and a displaceable projecting portion, and wherein the contact portion has
a recess for receiving the fixed projecting portion, but not the displaceable projecting portion, when the assay device is correctly positioned in the reading device; and
an interface portion that contacts and displaces the displaceable projecting portion when the assay device is correctly positioned in the reading device.

34. (previously presented) The test kit of claim 33, wherein the reading device further comprises means for pressing an assay device inserted into the reading device against the switch actuator.

35. (previously presented) The test kit of claim 34, wherein the reading device further comprises a cam that deflects the assay device away from the switch actuator unless the assay device is correctly positioned within the reading device.

36. (currently amended) The test ~~device~~ kit of claim 35, wherein the assay device is elongate, and wherein the reading device has a slot into which the assay device is at least

Appln No.: 08/935,717

Amendment Dated: June 25, 2004

Reply to Office Action of March 25, 2004

partially inserted through a mouth for reading of the assay device, and wherein the slot has at least one projecting lip portion extending over the mouth of the slot, said lip portion acting to retain the assay device within the slot when correctly positioned therein.